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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,680	07/18/2003	Tsuneo Hiraide	p23560.dc1.doc	1781

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EXAMINER

JACKSON, MONIQUE R

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,680

Applicant(s)

HIRAIDE ET AL.

Examiner

Monique R Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/6/04 & 1/20/04 & 10/20/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 includes three parenthetical expressions rendering the claims indefinite because it is unclear whether the limitations within the parentheses are meant to be part of the claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-38 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Nagai (USPN 4,904,534) in view of Tomonaga et al and in further view of EP 215 or IE 833. Nagai teaches an implant material excellent in biocompatibility and mechanical properties comprising a metallic material and a layer of resin and hydroxyapatite formed around the metallic material (Abstract.) Nagai teaches that the grain size of hydroxyapatite is less than 1000 micrometers in diameter (*reads on both calcium phosphate particles and a calcium phosphate "block"*), preferably in the range of from 0.01 to 100 micrometers from the viewpoints of processability,

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handling and mechanical strength (Col. 3, lines 27-31.) Nagai teaches that the shape and size of the metallic material are not specifically limited, and the shape can be pin-type, screw-type, blade-type, anchor-type, etc., with a cross-section of square, circle, oval, etc., and that the metal may be stainless steel and titanium or alloys thereof (Col. 3, lines 33-49.) The implant material may be produced by molding a mixture of the hydroxyapatite, powdery or granular thermosetting resin, and monomer, and then selecting the appropriate conditions of hardening such as temperature and time to produce the composite implant material (Col. 3, line 50-Col. 4, line 16.) Nagai further teaches that known methods of producing similar implant materials include the use of thermoplastic polymers but that the thermoplastic polymers are insufficient in the adhesion to the metallic material, the stability in living body, and the mechanical properties and hence a thermosetting resin provides improved properties (Col. 1, lines 56-68.) Though Nagai does not teach the use of a mixture of thermoplastic and thermosetting resin particles, considering it is known in the art that either thermoplastic or thermosetting materials may be utilized (as taught by Nagai or Tomonaga et al) and that a mixture of such resins have been utilized to produce for implant materials (EP'215 or IE 833), it would have been obvious to one having ordinary skill in the art to utilize a mixture of thermoplastic and thermosetting resins based on the desired properties such as mechanical properties and metal adhesion, and intended end use of the composite material. Though Nagai does not specifically teach that the hydroxyapatite include a block of 1mm or more thickness, one having ordinary skill in the art at the time of the invention would have been motivated to determine the optimum size of the hydroxyapatite particles given that the size, as taught by Nagai, is a result-effective variable affecting the processability, handling and mechanical strength of the resulting composite. Nagai teaches that the

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hydroxyapatite used in the invention may be synthetic, natural, a calcined product thereof or a mixture thereof wherein though Nagai does not teach the ratios as instantly claimed, one having ordinary skill in the art at the time of the invention would have been motivated to utilize routine experimentation to determine the optimum ratio of calcium to phosphate and optimum amount of resin to provide the desired properties such as biocompatibility and mechanical properties for a particular end use. It is also noted that one skilled in the art could easily determine suitable molding conditions, such as temperature, to produce a final molded product wherein the final product could be tailored in terms of shape, size, etc. for a particular end.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/615013 in view of Nagai (USPN 4,904,534.) Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art to incorporate a metal member into the calcium phosphate-synthetic composite of the copending application to provide reinforcement to

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the composite as taught by Nagai, including stainless steel and titanium alloys, utilizing any desired shape based on the shape of the final product, to determine the optimum amount of calcium phosphate to resin to utilize, and further to utilize typical molding steps as instantly claimed to produce the molded article.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique R Jackson whose telephone number is 571-272-1508. The examiner can normally be reached on Mondays-Thursdays, 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Monique R. Jackson
Primary Examiner
Technology Center 1700
June 12, 2005